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10/587,734	05/17/2007	Andrew Ian Cooper	T3111(C)	2517
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EXAMINER KRYLOVA, IRINA				
ART UNIT		PAPER NUMBER		
1796				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentgroupus@unilever.com

### Office Action Summary

**Application No.**

10/587,734

**Applicant(s)**

COOPER ET AL.

**Examiner**

Irina Krylova

**Art Unit**

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-9 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 and 21 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed by Applicant on May 13, 2010 has been fully considered. The Terminal Disclaimer filed by Applicant on May 13, 2010 is acknowledged. In light of the Terminal Disclaimer, the obvious type double patenting rejection over a copending Application 10/587,732 is withdrawn. The amendment to claims 1, 3, 4, 7, 9 and 21; cancellation of claims 2, 10-20 are acknowledged. Specifically, claim 1 has been amended to include the limitations of the porous bodies being oil-in-water emulsion-formed; being water-soluble, containing hydrophobic materials; comprising two specified types of pores and the bodies being in the form of powders, beads and moulded bodies. These limitations in their combination were not previously presented and were taken from instant claim 2, now cancelled, and instant specification (see p. 2, lines 1-20; p. 4, lines 5-7; 28-34; p. 5, lines 1-4; p. 9, lines 26-28; p. 11, lines 29-34). In light of the amendment filed by Applicant on May 13, 2010, all previous rejections are withdrawn. The new grounds of rejections necessitated by Applicant's amendment are set forth below. Thus, the following action is properly made final.

### ***Claim Objections***

2. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 is dependent on claim 1 and

recites the specific Markush-type list of water-insoluble materials. However, instant claim 1 does not mention the porous bodies comprising water-insoluble material, but rather hydrophobic material without specifying solubility.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**3. Claims 1-3, 5-9, 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Seth et al** (US 4,721,709).

4. The discussion with respect to **Gregory et al** (US 4,371,516) is set forth on pages 9-11 of an Office Action mailed on January 14, 2010 and is incorporated here by reference.

5. With respect to the additional limitations as presented in amended claim 1, **Gregory et al** discloses that shaped articles, which appear to be produced in a mould (col. 4, lines 29-30; col. 3, lines 60-61) and thus are being moulded articles, are prepared by subliming solvent from composition comprising the chemical and a solution of a carrier material in a solvent (col. 3, lines 57-68), wherein the solvent is preferably

water but it may contain a co-solvent to improve solubility of the chemical (col. 3, lines 68-69; col. 4, lines 1-2). Thus, it would have been obvious to a skilled artisan that depending on the specific drug, i.e. hydrophilic or hydrophobic, a specific co-solvent appropriate for increasing solubility of that drug, should be used. Since **Gregory et al** discloses the use of such drug as clonazepam (col. 3, lines 33) and clonazepam is a hydrophobic drug which is known to be adsorbed onto a carrier to form adsorbate, followed by freeze-drying (see col. 7, lines 48-55; col. 13, lines 45-65 of **Seth et al**), therefore, it would have been obvious to a skilled artisan to use as an oil-based co-solvent that will improve the solubility of hydrophobic drug clonazepam, in the process of **Gregory et al** as well. Though not recited explicitly by **Gregory et al**, however, combination of water, oily-based co-solvent and a surfactant (col. 4, lines 1-7) appears to produce oil-in-water emulsion as well. Further, it is noted that the oil phase (and preparation of oil-in-water emulsion) disclosed in the instant invention is used for the same purpose as that of **Gregory et al**, i.e. to improve solubility of hydrophobic materials (see p. 4, lines 28-34 of the instant invention). Since **Gregory et al** discloses the porous moulded articles produced by freeze-drying the composition comprising a chemical and a carrier material including a water solvent and a co-solvent (which in the case of the hydrophobic drug will be an oily phase), therefore, it would have been obvious to a skilled artisan that freeze-drying of the composition will produce pores from both water phase and an oil phase as well.

6. In addition, the limitation of "oil-in-water emulsion-formed" lattice is a product by process limitation. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. In the present case, the recited steps imply a structure having porous bodies containing hydrophobic material. The reference suggests such a product. Claim 21 is product by process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113.

**7. Claims 1-3, 5-9, 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857).

8. The discussion with respect to **Gregory et al** (US 4,371,516) is set forth on pages 9-11 of an Office Action mailed on January 14, 2010 and is incorporated here by reference.

9. With respect to the additional limitations as presented in amended claim 1, **Gregory et al** discloses that shaped articles, which appear to be produced in a mould (col. 4, lines 29-30; col. 3, lines 60-61) and thus are being moulded articles, are prepared by subliming solvent from composition comprising the chemical and a solution of a carrier material in a solvent (col. 3, lines 57-68), wherein the solvent is preferably water but it may contain a co-solvent to improve solubility of the chemical (col. 3, lines

68-69; col. 4, lines 1-2). Thus, it would have been obvious to a skilled artisan that depending on the specific drug, i.e. hydrophilic or hydrophobic, a specific co-solvent appropriate for increasing solubility of that drug, should be used. **Gregory et al** discloses the use of such drug as ethynyl oestradiol (col. 3, lines 36). Oestradiol is known in the art to be a hydrophobic drug (as disclosed by **Haynes et al** in col. 4, lines 34-36). Though **Gregory et al** does not explicitly state the lattice being formed from oil-in-water emulsion and specify the porous bodies having two types of pores as recited in instant claim 1, however, **Haynes et al** further discloses a process for preparing a composite comprising preparing an oil-in-water-emulsion followed by freeze drying the emulsion (col. 2, lines 40-42) to form a sponge (col. 2, lines 30-31). The oil phase is used for dissolving oestradiol hydrophobic drug (col. 4, lines 34-36; col. 2, lines 50-51). The composition comprises sorbitan ester and polysaccharide emulsifiers (col. 4, lines 1-8).

10. Since **Gregory et al** discloses the presence of appropriate co-solvent to improve solubility of the drug, including hydrophobic drug oestradiol, and **Haynes et al** discloses the use of oil to dissolve the hydrophobic drug, prepare an oil-in-water emulsion followed by freeze drying the emulsion to form a sponge, therefore, it would have been obvious to a one of ordinary skill in the art at the time of the invention was made to combine teachings of **Gregory et al** and **Haynes et al**, i.e. use an oil phase to improve solubility of hydrophobic drug and prepare an oil-in-water emulsion followed by freeze drying, as taught by **Haynes et al**, in the process of Gregory et al to further improve

solubility of hydrophobic drugs of **Gregory et al**, and thus arrive at the present invention.

11. Since the porous moulded bodies of **Gregory et al** in view of **Haynes et al** are identical to those claimed in the instant invention and are produced by freeze drying of an oil-in water emulsion containing a hydrophobic drug, therefore, the porous bodies of **Gregory et al** in view of **Haynes et al** will intrinsically contain pores of two types, i.e. produced from sublimation of solid ice from water phase and from sublimation of oil phase and, further will have an intrusion volume as claimed in the instant invention, as well. "Products of identical chemical composition can not have mutually exclusive properties" (See MPEP 2112.01).

12. Since both **Gregory et al** and **Haynes et al** stated that the surfactant (or emulsifiers) aid in dispersion of the chemical and prevents the freeze dried product from sticking to mold (see col. 4, lines 1-8 of **Haynes et al**), therefore, the specific amount of the surfactant present in the composition becomes a result effective variable, therefore, it would have been obvious to one skilled in the art at the time of the invention was made, to make variations in the content of the surfactant to obtain the desired degree of dispersing of the chemical in aqueous medium. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

13. In addition, the limitation of "oil-in-water emulsion-formed" lattice is a product by process limitation. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps.



See MPEP 2113. In the present case, the recited steps imply a structure having porous bodies containing hydrophobic material. The reference suggests such a product. Claim 21 is product by process claims. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113.

**14. Claims 1, 3-9, 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), as applied to claim 1, in further view of **Gole et al** (US 5,648,093), **Unger et al** (US 5,502,082) and **Fujimoto** (JP 01011141).

15. The discussion with respect to **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857) set forth in paragraphs 7-13 above, is incorporated here by reference.

16. **Gregory et al** in view of **Haynes et al** do not teach the porous articles comprising cellulose material such as hydroxyethylcellulose or sodium salt of carboxymethylcellulose, the specific ratio between the polymer and a surfactant.

17. **Gole et al** discloses a fast dissolving solid porous dosage form comprising:

A) 0.1-15% wt of matrix material (col. 2, lines 54-63) comprising hydroxyethylcellulose, sodium carboxymethylcellulose and xanthan gum (col. 6, lines 35-67);

B) a surfactant (col. 6, lines 8-10);

C) an active agent,

wherein an active agent comprises a water-insoluble pigment (col. 13, lines 30-45) and the dosage is produced by lyophilization process (col. 2, lines 54-55).

18. The specific example discloses spheres produced by freeze drying of an aqueous solution containing 4%wt of a gelatin (as a polymer carrier); 3% mannitol and 1% of sodium diethylsulfosuccinate as a surfactant (col. 15, lines 65-67; col. 1, lines 1-15). Since no other ingredients besides gelatin (as a polymer carrier); mannitol and sodium diethylsulfosuccinate, therefore, it would have been obvious to a one of ordinary skill in the art at the time of the invention was made that the ratio between these components will be: 12.5 parts of surfactant to 87.5 parts of polymer (gelatin and mannitol).

19. The solid carrier system may be added to a medium to obtain a solution or dispersion of the desired concentration (col. 4, lines 17-20).

The resulting preparation exhibits high porosity while having sufficient strength (col. 4, lines 24-27).

20. **Unger et al** discloses highly porous body having an open celled three-dimensional lattice structure produced by freeze drying of a composition comprising hydroxyl containing polymers, such as polysaccharides, vinyl alcohols (col. 5, lines 2-20) and a surfactant as a pore controlling agent (col. 11, lines 42-50) to maximize pore volume.

**21. Fujimoto** discloses porous article produced from a mixture of 0.05-50% of a hydrophilic polymer (such as cellulose or polyvinyl alcohol) and 0.5-50% of a surfactant, by freeze drying the mixture, wherein the product has a thickness of 5-100mm (Abstract) and the pores are adjustable by the amount of a surfactant (Abstract).

22. Since

1) **Gregory et al** in view of **Haynes et al** disclose shaped articles having a porous open matrix network of water-soluble carrier, the articles carrying a chemical and being rapidly disintegrated by water comprising a polymer and a surfactant, but do not teach the porous articles comprising cellulose material and the specific ratio between the polymer and a surfactant;

**2) Gole et al** discloses a fast dissolving solid porous dosage form comprising 0.1-15% wt of matrix material comprising hydroxyethylcellulose, a surfactant and an active agent, wherein the ratio between the surfactant and the polymer being 12.5 parts of surfactant to 87.5 parts of polymer; the resulting preparation exhibits high porosity (col. 4, lines 24-27);

3) both **Unger et al** and **Fujimoto** disclose highly porous body produced by freeze drying method, specifically teaching that surfactant is used a pore controlling agent to maximize pore volume (col. 11, lines 42-50 of **Unger et al** and Abstract in **Fujimoto**); therefore, it would have been obvious to a one of ordinary skill in the art at the time of the invention was made to use to combine teachings of **Gregory et al** in view of **Haynes et al** with teachings of **Gole et al** and to use cellulose derivatives as water-

soluble matrix polymers in the process of **Gregory et al** in view of **Haynes et al** as well since it would have been obvious to substitute one equivalent for another. Case law holds that the selection of a known material based on its suitability for its intended use supports prima facie obviousness. *Sinclair & Carroll Co vs. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1045). Case law holds that the mere substitution of an equivalent (something equal in value or meaning, as taught by analogous prior art) is not an act of invention; where equivalency is known to the prior art, the substitution of one equivalent for another is not patentable. See *In re Ruff* 118 USPQ 343 (CCPA 1958). Furthermore, based on the teachings of **Gole et al**, **Unger et al** and **Fujimoto** that surfactant is used as a pore controlling agent, it would have been obvious to a skilled artisan to make variations in the amount of used surfactant and adjust the ratio between the polymer and surfactant to produce porous bodies of **Gregory et al** in view of **Haynes et al** having desired pore volume as well. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05 II).

### ***Response to Arguments***

23. Applicant's arguments filed on May 13, 2010 have been fully considered. It is noted that in light of Applicant's amendment filed on May 13, 2010, all previous rejections are withdrawn, thus rendering Applicant's arguments moot.

24. Regarding the rejection of Claims 1-3, 5-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516), Applicant argues that **Gregory et al**

discloses freeze-drying of a single phase composition (not oil-in-water emulsion) and there is no disclosure of porous bodies having two different type of pores.

25. Examiner disagrees.

**Gregory et al** discloses porous moulded articles containing chemicals, such as pharmaceutical substances, including hydrophobic drugs, produced by sublimation of a composition comprising the chemical and a carrier in a solvent and co-solvent, wherein the co-solvent is used to improve solubility of the chemical. Given the pharmaceutical substance is a hydrophobic drug, such as oestradiol or clonazepam, the used co-solvent should be oily in order to improve solubility of the drug. Thus, combination of hydrophobic drug in an oil phase, water and a surfactant would lead to formation of oil-in-water emulsion, and thus freeze-drying of oil-in-water emulsion will appear to take place. Since the sublimation of oil-in-water emulsion containing a hydrophobic drug of **Gregory et al** is identical to that claimed in the instant invention, therefore, the pore type of the porous moulded article of **Gregory et al** will be identical to that claimed in the instant invention. Furthermore, the newly applied secondary reference of **Haynes et al** (US 5,660,857) further teaches the freeze drying of oil-in-water emulsions containing hydrophobic drugs. Specifically, see discussion in paragraphs 7-13 above.

26. Regarding the rejection of claims 1, 3-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of in view of **Haynes et al** (US

5,660,857), **Gole et al** (US 5,648,093), **Unger et al** (US 5,502,082) and **Fujimoto** (JP 01011141), Applicant argues that:

- a) **Gole et al** discloses a dosage form formed by subjecting a matrix-solution to lyophilization or solid-state dissolution which are different techniques.
- b) **Unger et al** discloses cross-linked porous bodies that are not water-soluble.

27. Examiner disagrees.

1) **Gole et al** discloses a dosage form formed by subjecting a matrix material to lyophilization or solid-state dissolution (col. 2, lines 54-55). It is noted that these techniques are used alternatively. In col. 1, lines 24-35, **Gole et al** recites that the conventional methods of freeze-drying or lyophilization of aqueous solutions and suspensions containing bioactive ingredients involve freezing of a material followed by dehydration by sublimation under high vacuum (col. 1, lines 24-35). Thus, the lyophilization method of **Gole et al** includes sublimation as well. Though the process of **Gole et al** includes an additional step of coating active agent with a protective coating, however, **Gole et al** is a secondary reference which was applied to show that freeze drying (i.e. sublimation) of hydroxyethylcellulose and sodium salt of carboxymethylcellulose matrix, leads to preparations having high porosity. Therefore, cellulose derivatives can be used to prepare porous bodies of **Gregory et al** in view of in view of **Haynes et al** as well. Secondary reference does not need to teach all limitations. "It is not necessary to be able to bodily incorporate the secondary reference

into the primary reference in order to make the combination." *In re Nievelt*, 179 USPQ 224 (CCPA 1973).

2) Though **Unger et al** discloses an additional step of cross-linking of porous bodies, however, **Unger et al** is a secondary reference which was used to show that surfactant is used as a pore controlling agent to maximize pore volume (col. 11, lines 42-50) and thus it would have been obvious to a skilled artisan to make variations in the amount of surfactant used to make porous articles of **Gregory et al** in view of in view of **Haynes et al** to produce porous bodies having desired pore volume. "It is not necessary to be able to bodily incorporate the secondary reference into the primary reference in order to make the combination." *In re Nievelt*, 179 USPQ 224 (CCPA 1973).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina Krylova whose telephone number is (571)270-7349. The examiner can normally be reached on Monday-Friday 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasudevan Jagannathan can be reached on (571)272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Irina Krylova/  
Examiner, Art Unit 1796

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Supervisory Patent Examiner, Art Unit 1796



